510(k): ACE® Nancy Nail™ K032687

510(k) Summary 10-6-03

Name of Sponsor:	**DePuy ACE®, Inc.** 700 Orthopaedic Drive Warsaw, Indiana 46581-0988 Est. Reg. No.1818910
510(k) Contact:	**Rhonda Myer** Regulatory Affairs Phone: (574) 371-4944 FAX: (574) 371-4987
Trade Name:	**ACE® Nancy Nail™**
Common Name:	Intramedullary Elastic Nail
Classification:	**Class II** Device per 21 CFR 888.3040: Smooth or threaded metallic bone fixation fastener
Device Product Code:	**87 HTY**
Substantially Equivalent Devices:	**DePuy ACE® Nancy Nail™** **K960642** **Synthes Elastic Intramedullary Nail System** **K971783**
Device Description:	The **Nancy Nail™** is a titanium alloy pin that is implanted to facilitate the fixation of long bone fractures. The **Nancy Nail™** is available in two lengths; the 450 mm is available in five diameters (2.0, 2.5, 3.0, 3.5, 4.0 mm), and the 100 mm is available in 1.0 mm diameter. The **Nancy Nail™** is a single-use device intended for temporary implantation. It is intended to be removed once the bone has healed.

510(k) Summary (continued)

Indications for use: The 450 mm **Nancy Nail™** is intended as a temporary implant to aid in the healing of long bone (tibia, humerus, femur, etc.) fractures at diaphyseal, metaphyseal and epiphyseal levels. It is intended for use in children above four years of age and in any patient below 65 kg. The 100 mm **Nancy Nail™** is designed to treat fractures of small long bones with long diaphyses such as carpal or tarsal bones. **The 450 mm Nancy Nail™ is also intended for use in upper extremity fractures in all patients.**

This submission covers the additional indication for use in upper extremity fractures in all patients.

This indication has been cleared previously for the Synthes Elastic Intramedullary Nail System, K971783.

Substantial equivalence: Based on similarities of design, materials, and indications for use, DePuy believes the **ACE® Nancy Nail™** is substantially equivalent to the Synthes Elastic Intramedullary Nail System, K971783.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 6 2003

Ms. Rhonda Myer
Regulatory Affairs
DePuy Orthopaedics, Inc.
P.O. Box 988
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

Re: K032687
Trade/Device Name: ACE® Nancy Nail™
Regulation Number: 21 CFR 3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HTY
Dated: August 28, 2003
Received: August 29, 2003

Dear Ms. Myer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K032687

Device Name: ACE® Nancy Nail ™

Indications for Use:

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Concurrence of CDRH, Office of Device Evaluation

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

(k) Number K032687

Prescription Use_____ OR Over-The-Counter Use
(Per 21 CFR 801.109)